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COMPANY, INC.

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/
Counterclaim-Defendant

vs.

INTUITIVE SURGICAL, INC.,

Defendant/
Counterclaimant.

Case No.: 3:21-cv-03496-AMO-LB

UPDATED JOINT CASE MANAGEMENT STATEMENT

Judge: The Honorable Araceli Martínez-Olguín

In accordance with Civil Local Rule 16-9, the Standing Order for All Judges of the Northern District of California: Contents of Joint Case Management Statement, Standing Order For Civil Cases Before District Judge Araceli Martínez-Olguín, and the Order Reassigning Case (Dkt. 159), Plaintiff Surgical Instrument Service Company, Inc ("SIS") and Defendant Intuitive Surgical, Inc. ("Intuitive") met and conferred regarding the topics set forth in Civil Local Rule 16-9 and by and through their respective attorneys of record, hereby submit the following Updated Joint Case Management Statement (the "Updated Statement"). This Updated Statement updates the following, all of which are attached as exhibits: (1) Joint Case Management Statement dated August 4, 2021 (Dkt. 36); (2) Joint Case Management Statement dated September 21, 2022 (Dkt. 96); (3) Joint Stipulation and Order to Modify Case Schedule (Dkt. 90); and (4) Joint Stipulation and Order to Modify Summary Judgment Briefing Schedule (Dkt. 115). *See* Exhibits A-D.

1. Jurisdiction and Service

This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 15, 22, and 1121. The Parties do not dispute personal jurisdiction, venue, or service.

2. Facts

SIS's Statement: Intuitive developed its da Vinci system in the mid-to-late 1990s. Although modest changes have been made to the system since then, Intuitive's products, and its business model, have changed little since that initial development. The systems themselves include a "robot" and associated "console" that are used to perform minimally invasive surgery with only a small number of small incisions. A variety of surgical instruments are inserted via "trocars" into a surgical field, and the surgical field and movement of instruments within that surgical field are monitored by a small camera. Compared to traditional laparoscopic surgery where the surgeon and surgical staff physically hold and manipulate the instruments, in a da Vinci system the instruments such as scalpels, forceps, grippers, and the like attach to movable arms of the da Vinci robot, and are controlled remotely by a surgeon sitting at the da Vinci console. Intuitive has an absolute monopoly in robotic systems for performing minimally invasive surgery, with over 99% of the market.

This lawsuit relates to the instruments that attach to the robot arms, called EndoWrists. These are mechanical instruments that have circular disks that interface with motors within the robot arms, which in turn manipulate the tools at the end instruments about multiple degrees of freedom to perform surgical operations based on the surgeon's commands from the console. The physical design of the EndoWrists is largely unchanged in the 25+ years since their early development – ever since their introduction, four disks are turned by a motor in a robot arm, and pulleys and cables of the EndoWrist translate that to movement of the tool-end device. As Intuitive itself agrees, EndoWrist designs are virtually "identical" over the years.

Surgical Instrument Service Company has over 50 years of experience in repairing surgical instruments, some of which are substantially more complex than EndoWrists. But with EndoWrists there is a catch – Intuitive has created a self-destruct use counter that prevents EndoWrist from being used more than a set number of times, typically 10. This self-destruct is unique to Intuitive and bears no relation to the actual wear and tear or lifetime of the device. Indeed, third-party testing and Intuitive's own data confirm that EndoWrists can be used many more times, particularly when repaired with a robust process such as the process SIS was implementing.

Intuitive has wielded its monopoly power to prevent a repair market in EndoWrists from existing. Intuitive's abuse of its monopoly power is notorious in the health care industry, but hospitals and surgeons have no choice. Intuitive's self-destruct values are set by its marketing department to maximize profits, to the tune of billions of dollars annually for EndoWrists alone. When SIS business partners discovered a way around the self-destruct counter, in a manner that would save hundreds of millions of dollars a year for hospitals and patients, SIS began marketing the EndoWrist repair program to its nationwide customer base. It signed contracts with major hospital systems, including in this district, and also as the sole supplier of EndoWrist repair to a Group Purchasing Organization representing over 2000 hospitals.

Faced with this threat to its monopoly profit machine, Intuitive threatened to shut down hospitals' entire robot surgery programs if they used repaired EndoWrist instruments. In the case of one SIS customer, this represented over 40 robots and tens of millions of dollars of capital investment. Perhaps recognizing that its own data shows that EndoWrists are suitable for repair well

past the limits of its self-destruct mechanism, Intuitive's latest justification for its anticompetitive conduct is a claim that the EndoWrist repair service constitutes "remanufacturing" and requires a burdensome, separate, FDA approval process. But FDA and Intuitive's own trade organizations disagree. Over the last decade, FDA has engaged in substantial outreach and discussion to *create* standards for what constitutes "remanufacturing", but still has not done so. Frustrated by FDA's failure to do the OEMs bidding to effectively outlaw the third-party repair industry, OEMs have twice tried and failed to pass legislation that would accomplish what Intuitive has accomplished via its monopoly power.

Intuitive's Statement: Intuitive manufactures sophisticated medical devices used to perform surgery. Its da Vinci systems are often referred to as "robotic" surgical systems, as they allow a surgeon to operate from a console that permits the surgeon to control "EndoWrist" surgical instruments attached to mechanical arms suspended above the patient. Da Vinci systems allow surgeons to perform procedures with significantly reduced trauma and improved patient outcomes compared with other modes of surgery, including fewer complications and faster recovery times. EndoWrist instruments are unique because they mimic and even exceed the range of motion of the human wrist, allowing surgeons to move an instrument inside the body to desired angles with great precision. This flexibility requires use of fine wire cables that thread through a complex pulley system. While this design yields tremendous benefits for surgeons and patients, it comes at the cost of making the instruments susceptible to wear and tear with repeated use and the harsh sterilization cycles required between surgeries. As a result, unlike traditional surgical instruments, EndoWrists are at increased risk of failure after only a modest number of uses, which can in turn pose risk of injury to patients.

Da Vinci systems and EndoWrists are Class II medical devices for which Intuitive was required to make a detailed showing of safety and effectiveness to obtain "clearance" from FDA before the instruments could be marketed and used on patients. From the beginning, Intuitive realized that to make this showing, EndoWrists would need to be subject to strict use limits. Intuitive therefore performed extensive testing on EndoWrists to evaluate the number of uses that could be tolerated without exceeding statistical targets for failure. The resulting data, along with the use limits generated based on the data and instrument design components that would ensure compliance with those limits, were

submitted to FDA – in submissions referred to as "510(k) submissions." These submissions included the design element of a "use counter" in each EndoWrist that tracks the number of times it has been used and disables the instrument after its final approved use is reached. FDA provided "clearance" to the instruments based on its review of Intuitive's 510(k) submissions. This clearance covers only instruments with their original physical and functional attributes, including the use counter operating as originally designed and cleared by FDA. Over the past decade, FDA has repeatedly made clear that any material change to these instruments – including to bypass or change the use counter – is considered "remanufacturing." FDA regulations require remanufacturers to obtain 510(k) clearance before hospitals may lawfully use remanufactured devices on patients in a clinical setting.

Many years after Intuitive's systems and instruments were first introduced into the market, third parties tried to hack into Intuitive's EndoWrists to bypass the use limits. Intuitive objected to this remanufacturing activity, as did FDA, which instructed the remanufacturers to cease. After disputing with the agency about the need for clearance, they ceased operation. Meanwhile, Intuitive had reached out to a few customers who were using remanufactured EndoWrists to explain the safety risks for patients associated with the use of remanufactured instruments that lacked FDA clearance. Intuitive also pointed to a provision in its contracts that prohibited use of non-approved instruments with the da Vinci system. Intuitive has never tried to interfere with a hospital customer who sought to use an FDA-cleared remanufactured EndoWrist. SIS has never performed any remanufacturing services on EndoWrists. Instead, it operated briefly as a distributor for a third party that engaged in remanufacturing EndoWrists without FDA clearance.

3. Legal Issues

Please see Exhibit A at 6-7.

4. Motions

Intuitive filed a motion to dismiss all claims (Dkt. No. 37), which Judge Vince Chhabria denied except as to one portion of SIS's Lanham Act claim (Dkt. No. 70). Intuitive also filed a motion to stay this case (Dkt. No. 46), which Judge Chhabria denied (Dkt. No. 61). Cross-motions for summary judgment and related *Daubert* motions are fully briefed.

On May 10, 2023, the Court issued an order re-assigning these coordinated actions from the Honorable Vince Chhabria to the Honorable Araceli Martínez-Olguín (the "Order"). On May 15, 2023, the Parties filed a stipulation in which they proposed re-noticing the pending motions for June 8, 2023, the previously scheduled hearing date, unless the Court was unavailable, in which case the Parties agreed to propose alternative hearing dates in this filing. (Doc. No. 174.) The Parties understand that the Court is not available on June 8, and thus plan to notice the hearing on the pending summary judgment and *Daubert* motions for August 31, 2023.

5. Amendment of Pleadings

The deadline to file amended pleadings has passed. The Parties do not anticipate any amendments of the pleadings.

6. Evidence Preservation

The Parties certify that they have reviewed the Guidelines Relating to the Discovery of Electronically Stored Information ("ESI Guidelines") and have met and conferred pursuant to Fed. R. Civ. P. 26(f) regarding reasonable and proportionate steps taken to preserve evidence relevant to the issues reasonably evident. The Parties have confirmed litigation holds are in place. On April 1, 2022, the Parties filed a Stipulated Order Re: Discovery of Hard-Copy Documents and Electronically Stored Information (Doc. No. 85), which the Court entered on April 4, 2022 (Doc. No. 86).

7. Disclosures

The parties fully and timely complied with the initial disclosure requirements of Fed. R. Civ. P. 26(a)(1) on August 26, 2021.

8. Discovery

Fact and expert discovery has been completed in this case. There are no pending or otherwise unresolved discovery disputes.

9. Class Action

This is not a class action.

10. Related Cases

Two antitrust class actions brought on behalf of Intuitive customers (*Larkin*, No. 3:21-cv-03825; and *Franciscan Alliance*, No. 3:21-cv-05198) were filed in 2021. On August 20, 2021, Plaintiffs moved

to consolidate those actions[1] and, on August 25, 2021, the Court granted Plaintiffs' consolidation motion and the matters were consolidated in No. 3:21-cv-03825 as *In re: Da Vinci Surgical Robot Antitrust Litigation*, which is pending before this Court. Intuitive intends to move to consolidate this case with *In re: Da Vinci Surgical Robot Antitrust Litigation* for trial should one be necessary.

SIS's statement: There were two additional antitrust actions that were filed in Florida district courts and are now concluded by settlement just before trial: (1) *Restore Robotics LLC v. Intuitive Surgical, Inc.*, No. 5:19-cv-55-TKW-MJF, before Judge T. Kent Wetherell II in the Northern District of Florida; and (2) *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, No. 8:20-cv-02274-VMC-TGW, before Judge Virginia Covington in the Middle District of Florida. In prior Case Management Statements Intuitive characterized the claims and factual allegations as "nearly identical" to those presented here. In both Florida actions, cross motions for summary judgment were submitted and decided,[2] along with numerous Daubert motions to exclude expert testimony.[3]

Intuitive's Statement: Intuitive intends to move to consolidate this case with the *In re: Da Vinci Surgical Robot Antitrust Litigation* for trial should one be necessary. The Florida cases have been fully

[1] At the time the consolidation motion was filed, there was a third action, brought by then-Plaintiff Kaleida Health. That party, however, filed a notice of voluntary dismissal on January 14, 2022 (Doc. No. 72).

[2] In the *Restore* case, the court granted Intuitive summary judgment as to the claims asserted by Clif Parker Robotics dealing with unused or partially used EndoWrists, granted Restore summary judgment as to Intuitive's CFAA counterclaim and the 510(k) clearance aspect of the false advertising counterclaim. In all other respects, the court ruled "that disputed issues *of* fact remain on nearly all the claims." Restore, 2022 WL 1495005. In the *Rebotix* case, cross motions for summary judgment were denied. Rebotix, 2022 WL 3272538.

[3] In the *Restore* case, the court granted Restore's Daubert motion to the extent of excluding the ultimate legal opinion on FDA regulatory compliance, any interpretations of FDA regulations that differ from FDA public interpretations, and any testimony as to perceptions of other doctors and patients in general. The court denied Intuitive's Daubert motion seeking to exclude Restore's antitrust / damages expert. Restore, 5:19-cv-00055-TKW-MJF, Dkt. 149 (N.D. Fla. Feb. 7, 2022). In the *Rebotix* case, the court denied Intuitive's Daubert motion to exclude the opinions of Dr. Russell Lamb on the antitrust issues and granted Intuitive's Daubert motion only with respect to Dr. Kim T. Parnell's opinion about laparoscopic instruments and his opinion that Intuitive has no basis to make a claim about the safety or reliability of modified EndoWrists. Ruling on the parties' Daubert motions dealing with exclusion of FDA experts' testimony, the *Rebotix* court excluded any opinions about Rebotix's compliance with FDA regulations, any opinions interpreting FDA regulations that differ from the FDA's public interpretations, and any opinions that rely on the Deutsche Bank report. Rebotix, 8:20-cv-02274-VMC-TGW, Dkt. 182-186 (M.D. Fla. Aug. 10, 2022).

resolved. Intuitive has shown in its summary judgment briefs that the summary judgment opinions in the Florida cases do not undermine Intuitive's entitlement to summary judgment in this case under governing law. SIS's descriptions of the *Daubert* decisions in Florida do not accurately capture those decisions, and Intuitive has cited the pertinent parts of those decisions in its *Daubert* motions here.

11. Relief

SIS seeks damages it asserts were caused by Intuitive's violations of the Sherman Act subject to mandatory trebling. 15 U.S.C. § 15. SIS also seeks damages it asserts were caused by Intuitive's violations of the Lanham Act, including disgorgement of profits and trebled damages. 15 U.S.C. § 1117(a). SIS may also seek injunctive relief, including preventing Intuitive from continuing the acts SIS asserts are in violation of the Sherman Act and Lanham Act. 15 U.S.C. §§ 1, 2, 26, and 1116. SIS also seeks costs, expenses, reasonable attorneys' fees, and post-judgment interest on all sums awarded. 15 U.S.C. §§ 15(a), 1117(a). Intuitive opposes all forms of relief sought by SIS.

Intuitive seeks damages it asserts were caused by SIS's violations of the Lanham Act and California's Unfair Competition Law, including disgorgement of profits. Intuitive may also seek injunctive relief, including preventing SIS from causing further deception and confusion among consumers. Intuitive also seeks costs, expenses, reasonable attorneys' fees, and post-judgment interest on all sums awarded. SIS opposes all forms of relief sought by Intuitive.

12. Settlement and ADR

To date, based on the respective positions of the parties and the condensed substantive case schedule between November 2022 – May 2023, including depositions of dozens of fact witnesses, expert reports, expert depositions, summary judgment briefing, and *Daubert* briefing, the parties do not believe ADR would be useful in narrowing the issues in the case or for potentially reaching a resolution.

13. Other References

The parties do not believe that this case is suitable for reference to binding arbitration, special master, or the Judicial Panel on Multidistrict Litigation.

14. Narrowing of Issues

The Parties do not believe that it is possible to narrow the issues by agreement at this time.

15. Expedited Trial Procedure

The Parties do not believe that this case is appropriate to be handled under the Expedited Trial Procedure of General Order 64.

16. Scheduling

The Parties' scheduling proposal for the hearing on the pending motions is discussed above. *Supra* § 4.

The current case schedule (Dkt. No. 90) does not set forth dates for the pretrial conference and trial.

SIS proposes that the pretrial conference occur on Thursday, October 12th at 11AM, with trial beginning on Tuesday, October 17.

Intuitive proposes that the Court adopt the approach of Judge Chhabria, who previously ordered that scheduling of deadlines beyond the hearing on the summary judgment and *Daubert* motions would not occur until those motions have been resolved. Aug. 11, 2021 Hr'g Tr. 14:20-25. Intuitive thus proposes that the Court hold a further case management conference two weeks after issuing its decision on the Parties' motions for summary judgment.

17. Trial

SIS's statement: SIS seeks a jury trial on all issues so triable. SIS estimates that a trial can be conducted in six (6) days, where each side is given fifteen (15) hours, excluding jury selection, opening statement, and closing argument. This case is not a class action case. SIS will oppose any effort by Intuitive to consolidate this case with the class action.

Intuitive's Statement: As noted above, Intuitive intends to file a motion to consolidate trial in this matter with the *Da Vinci Surgical Robot Antitrust Litigation*. Intuitive estimates that a consolidated trial would last 28 days on this Court's standard schedule. If the matters are not consolidated, Intuitive estimates that the trial in this case alone would last 20 days. Both estimates exclude jury selection, opening statements, and closing arguments. SIS's estimate of only six days is entirely unrealistic if one assumes, as Intuitive does for purpose of this Case Management Statement, that SIS is allowed to present evidence to support all of the claims in its Complaint, with Intuitive having a full opportunity to respond and to present its counterclaims. Moreover, SIS has proffered seven experts (with Intuitive proffering six experts collectively to respond to SIS's experts and to support Intuitive's counterclaims). And this is not a case

that can be tried for either side through expert testimony alone; much of each side's case – on both the claims and the counterclaims – will necessarily be presented through fact witnesses.

Based on the foregoing, Intuitive currently believes that, as the case is currently configured – before resolution of the pending summary judgment and *Daubert* motions – trial will require at least 100 hours on the record (exclusive of jury selection, opening statement, and closing arguments). Conversely, if the case is substantially narrowed through the Court's rulings on the pending motions, a shorter trial may be feasible. This further counsels in favor of deferring the setting of a trial date until the pending motions are resolved.

18. Disclosure of Non-Party Interested Entities or Persons

The parties have completed filing their "Certification of Interested Entities or Persons" as required by Civil Local Rule 3-15. Dkt. 24, 41.

19. Professional Conduct

All attorneys of record for the parties have reviewed the Guidelines for Professional Conduct for the Northern District of California.

Dated: May 31, 2023

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E-Filing Attestation

I, Richard McCaulley, am the ECF User whose ID and password are being used to file this document. In compliance with Civil Local Rule 5-1(i)(3), I hereby attest that each of the signatories identified above have concurred in this filing.

/s/ *Richard T. McCaulley*